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510(k) Summary

APR - 9 2007

Submitter Information

Allison Scott
11460 N. Meridian St., Suite 150
Carmel, IN 46032
Phone: (317) 569-9500 x106
Facsimile: (317) 569-9520

Contact Person: Allison Scott

Date: April 5, 2007

Trade Name: Foam Ring Port Protector

Common Name: Infusion Port Accessory

Classification Number: OBK

Device Description

The thickness of the foam ring, along with the hole in the center of the ring, aids in preventing things, such as seat belts, bra straps, and clothing, from rubbing against the embedded port. The product consists of one element; an off-white colored flat ring made out of non-latex hypoallergenic foam, with a die cut hole in the middle, with non-latex adhesive backing.

Intended Use(s)

The foam ring, with the hole in the center, may be used in conjunction with ports (e.g., chemotherapy, vascular, etc.), up to 1 3/8" (3.5 cm) in diameter and raising less than 3/8" above the skin.

The device is intended to cushion the localized area surrounding the port.

Performance Testing

Compression testing was conducted on the foam and peel strength testing was conducted with the adhesive.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Inspired Ideas, Incorporated
C/O Ms. Allison Scott
Official Correspondent
Anson Group, LLC
11460 North Meridian Street, Suite 150
Carmel, Indiana 46032

APR - 9 2007

Re: K062261
Trade/Device Name: Foam Ring Port Protector
Regulation Number: 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: OBK
Dated: March 27, 2007
Received: March 28, 2007

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

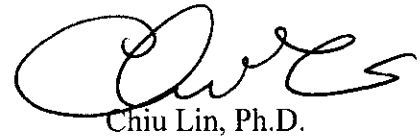
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062261

Indications for Use

510(k) Number (if known): _____

Device Name: Foam Ring Port Protector

Indications for Use:

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The device is intended to cushion the localized area surrounding the port.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Sign-Off)
General Hospital,

510(k) Number K062261